UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

December 23, 2011

NMED No. 110586 (CLOSED)

Mr. Mark Wrighton, Chancellor
Washington University in St. Louis
Campus Box 1192
One Brookings Drive
St. Louis, MO 63130

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03002271/11-003(DNMS) AND NOTICE OF VIOLATION – WASHINGTON UNIVERSITY IN ST. LOUIS

Dear Mr. Wrighton:

On November 16 through 18, 2011, a U. S. Nuclear Regulatory Commission (NRC) inspector conducted a reactive inspection at the Washington University St. Louis, Missouri facilities, with continued in-office review through November 28, 2011. The in-office review included receipt and review of information that was unavailable during the onsite inspection, including the licensee's written report of the medical event. The purpose of this inspection was to review the circumstances, root and contributing causes, and proposed corrective actions for a medical event that your staff reported to the NRC on November 3, 2011. The preliminary findings of the inspection were discussed with selected members of your staff at the conclusion of the on-site inspection and at a final, telephonic exit meeting with Susan Langhorst, Ph.D., Radiation Safety Officer (RSO), on November 28, 2011. The enclosed report presents the results of this inspection.

Based on the results of this inspection, the NRC has determined that a Severity Level IV violation of NRC requirements occurred. The violation was evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at (http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html). The violation is being cited in the enclosed Notice of Violation (Notice). The violation involves the failure to develop written procedures to provide high confidence that each administration of samarium-153 lexidronam is in accordance with the written directive. The violation is being cited because the NRC identified it.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC's review of your response to the Notice will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with Title 10 of the Code of Federal Regulations 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC

Agencywide Documents Access and Management System (ADAMS), accessible from the NRC website at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction.

Please contact Robert Gattone at (630) 829-9823 if you have any questions regarding this matter.

Sincerely,

/RA by Patrick L. Louden Acting for/

Anne T. Boland, Director
Division of Nuclear Materials Safety

Docket No. 030-02271
License No. 24-00167-11

Enclosures:
1. Notice of Violation
2. Inspection Report No. 03002271/11-003(DNMS)

cc w/ encls: Susan Langhorst, Ph.D., RSO
Bruce Backus, Asst. Vice Chancellor
State of Missouri

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Bruce Backus, Asst. Vice Chancellor
State of Missouri

DISTRIBUTION w/encls:
Jennifer Uhle, ORA
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NOTICE OF VIOLATION

Washington University in St. Louis
St. Louis, Missouri

Docket No. 030-02271
License No. 24-00167-11

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on November 16 through 18, 2011, with continued in-office review through November 28, 2011, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

> Title 10 of the Code of Federal Regulations (CFR) 35.41(a) states that, for any administration requiring a written directive, licensees are required to develop, implement, and maintain written procedures to provide high confidence that: (1) the patient's or human research subject's identity is verified before each administration; and (2) each administration is in accordance with the written directive. Procedures must meet the requirements described in 10 CFR 35.41(b).
>
> Contrary to the above, as of November 18, 2011, the licensee did not develop written procedures to provide high confidence that each administration is in accordance with the written directive. Specifically, the licensee's written procedures were silent regarding equipment considerations in preparation for and during dosage administrations.

This is a Severity Level IV violation (Section 6.3).

Pursuant to 10 CFR 2.201, Washington University in St. Louis is hereby required to submit a written statement or explanation for the violation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555, with a copy to the Regional Administrator, Region III, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for the violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid further violations; and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an Order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

Your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. Therefore, to the extent possible, it should not include any personal privacy or proprietary information so that it can be made available to the public without redaction. If personal privacy

or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information).

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated this 23rd day of December 2011

NUCLEAR REGULATORY COMMISSION

REGION III

Docket No.:	030-02271
License No.:	24-00167-11
Report No.:	03002271/11-003(DNMS)
Licensee:	Washington University in St. Louis
Location:	Barnes-Jewish Hospital 4921 Parkview Place St. Louis, Missouri
Dates of Inspection:	November 16 through 18, 2011, with continued in-office review through November 28, 2011
Inspection Procedure:	87131
Final Exit Meeting:	November 28, 2011
Inspector:	Robert G. Gattone, Jr., Senior Health Physicist
Reviewed By:	Tamara E. Bloomer, Chief Materials Inspection Branch Division of Nuclear Materials Safety

Enclosure 2

EXECUTIVE SUMMARY

Washington University in St. Louis
St. Louis, Missouri
Inspection Report 03002271/11-003(DNMS)

The inspector conducted a reactive inspection on November 16 through 18, 2011, at the Washington University in St. Louis, St. Louis, Missouri facilities, with continued in-office review through November 28, 2011, to review the events and circumstances associated with a medical event that the licensee reported to the NRC on November 3, 2011. The inspector determined that a medical event occurred as a result of inadvertent loss of about 66 percent of a prescribed samarium-153 lexidronam dosage before the remaining 34 percent of the prescribed dosage was administered to the patient. The licensee determined that the medical event would not result in adverse effects to the patient.

The root cause of the medical event was that the syringe containing the dosage started to slip out of the syringe shield during an attempt to connect the shielded syringe to the intravenous (IV) connector, resulting in inadvertent dosage loss when the Authorized User attempted to stop the syringe from slipping completely out of the syringe shield. Contributing factors to the medical event included: (1) the dosage's high specific activity; (2) the licensee's removal of the needle from the syringe without first pulling the material out of the needle and into the syringe; (3) the Authorized User's lack of experience with the syringe shield affixed to the syringe; (4) the inability of the syringe shield to secure the syringe within it; (5) the Authorized User's lack of training on how to prevent the syringe from disengaging from the syringe shield; (6) the decision to continue preparation for, and administration of, the dosage after identification of potential dosage leakage without first assessing the dosage radioactivity that was spilled; and (7) the failure to include response to potential leakage identified prior to dosage administration, the technique used to prevent syringe disengagement from the syringe shield, and response to syringe disengagement from the syringe shield in the licensee's written procedure titled, "Radiopharmacutical Handling and Injection and Administration Procedures" (Procedure).

The inspector identified a violation involving the licensee's failure to develop written procedures to provide high confidence that each administration is in accordance with the written directive.

The licensee implemented and/or planned corrective actions to prevent a similar event and a similar violation. To prevent a similar medical event, the licensee: (1) immediately established that only therapists with more experience connecting shielded syringes to the IV connector will do this until long-term corrective actions are developed and implemented; (2) began examining alternative syringe shield designs and ways to better secure the syringe in the syringe shield; and (3) began re-evaluating when to stop and assess the situation before administering dosages when there is indication of a potential problem that could result in a medical event. To prevent a similar violation, the licensee began to contemplate what revisions it would make to the Procedure to achieve compliance with the requirement.

Report Details

1 Program Scope and Inspection History

The NRC License, Number 24-00167-11, authorizes Washington University in St. Louis, a large broad scope medical licensee, to use, in part, samarium-153 lexidronam for bone pain treatments. The licensee conducted approximately 12 samarium-153 lexidronam treatments per year.

As a result of the NRC's last routine inspection that was conducted on January 24 through 27, 2011, a Severity Level IV violation was cited for the licensee's failure to secure from unauthorized removal or limit access to licensed materials that were stored in a controlled area.

As a result of the NRC's reactive inspection that was conducted on March 29 and 31, 2010, to review a potential overexposure, a Severity Level IV violation was cited for the licensee's failure to use tongs or tweezers, as appropriate, for the handling and use of licensed material.

As a result of the NRC's routine inspection that was conducted on February 22 through 25, 2010, the licensee was cited for a Severity Level IV, security-related violation.

No violations were identified during the NRC's routine inspection that was conducted on July 21, 2009.

2 Sequence of Events and Licensee Investigation

2.1 Inspection Scope

The inspector observed reenactments of the medical event and interviewed the authorized user (AU), the radiation safety officer (RSO), the referring physician, three radiation therapists (RT), two medical physicists (MP), two health physicists (HP), and other licensee personnel to determine the sequence of events that resulted in the medical event. In addition, the inspector reviewed selected licensee records, licensee procedures, and the licensee's compliance with regulatory requirements for samarium-153 lexidronam treatments.

2.2 Observations and Findings

a. Medical Event Details

On November 2, 2011, an AU signed and dated a written directive for intravenous (IV) administration of samarium-153 lexidronam to a patient for treatment of bone pain. The written directive dated November 2, 2011, contained the required information, including a prescribed dosage of 81 millicuries of samarium-153 lexidronam. The licensee received a unit dosage from its authorized radiopharmacy vendor containing 84.1 millicuries of samarium-153 lexidronam in 1.6 milliliters in a 10 cubic centimeters (cc) syringe.

The AU and two radiation oncology therapists were present during preparation for the dosage administration. An RT fitted a Huayi Isotopes Model 600292 Latchkey Beta/Gamma Syringe Shield to the syringe containing the dosage and provided the shielded syringe to the AU. The AU initially prepared to administer the dosage into the patient's IV line using the needle that was attached to the shielded syringe. Therefore, the AU removed the cap from the needle and noted that a drop of clear liquid was bulging from the needle tip, but the drop did not fall off of the needle. The AU then realized that the dosage must be administered by removing the needle and threading the shielded syringe into an IV connector. Therefore, the AU re-capped the needle, removed it from the syringe, and placed the capped needle into a small, plastic, radioactive waste container. The drop of clear liquid that bulged from the needle tip and did not fall off indicates that the needle contained a fraction of the dosage.

When attempting to connect the shielded syringe to the IV connector, the AU held the shielded syringe with the plunger side facing an absorbent-covered table below it. The syringe shield is designed such that the clockwise motion necessary to attach the syringe to the IV connector may result in the syringe slipping out of the syringe shield. The AU turned the syringe shield clockwise and noted that the syringe started to slip out of the syringe shield; therefore, the AU used one of her hands to stop the syringe from slipping completely out of the syringe shield. After attempting to prevent the syringe from slipping completely out of the syringe shield, the AU noticed some clear liquid on the surface of the shielded syringe near where the needle was connected to it.

The root cause of the medical event was that the syringe started to slip out of the syringe shield during an attempt to connect the shielded syringe to the IV connector, resulting in inadvertent dosage loss when the AU attempted to stop the syringe from slipping completely out of the syringe shield.

The AU decided to continue preparation for the dosage administration without first assessing the dosage that was spilled because: (1) the dosage contained about three millicuries more radioactivity than what was prescribed; therefore, the AU surmised that, if the clear liquid on the syringe surface was some of the dosage instead of saline (which is also clear), it would not likely result in more than ten percent less administered radioactivity versus prescribed; (2) although the AU couldn't see the dosage volume because of the syringe shield, the AU surmised that, since the amount of clear liquid on the surface of the shielded syringe near where the needle was connected to it was small, it would not likely result in more than ten percent less administered radioactivity versus prescribed.

An RT noticed clear fluid drip from the connector onto the absorbent cover below, but there was uncertainty if it was from the dosage, saline, or a combination of the two. The inspector determined that the dripped fluid was likely some of the dosage that was inadvertently expelled from the syringe when the AU attempted to stop the syringe from slipping completely out of the syringe shield. An RT offered to assist the AU, and the AU stepped back to allow the RT to complete the connection. The RT had more experience with handling the syringe shield affixed to the syringe compared to the AU. The AU didn't recall using the syringe shield prior to the medical event.

The syringe shield had an open slot to accept one of the two syringe tabs that was designed to prevent the syringe from disengaging from the syringe shield. The RT inserted the syringe into the syringe shield and turned the syringe clockwise to engage one of the two syringe tabs into the open slot of the syringe shield. The RT knew that the open slot did not secure the syringe in the syringe shield; therefore, the syringe could disengage from the syringe shield if the syringe shield was turned clockwise (resulting in the syringe turning counter-clockwise if it was not manually held in place by the person handling it). Therefore, the RT used her thumb to secure the syringe tab that was in the open slot of the syringe shield to prevent the syringe from turning counterclockwise and disengaging from the syringe shield. As a result, the RT was able to handle the shielded syringe without the syringe disengaging from the syringe shield. In addition, the RT was able to turn the shielded syringe clockwise to thread it into the IV connector without simultaneously disengaging the syringe from the syringe shield. The AU had not been trained on how to prevent the syringe from disengaging from the syringe shield. After the RT connected the shielded syringe to the IV connector, the AU administered the dosage to the patient and used saline to flush the shielded syringe four times without incident.

After the dosage administration, an RT gathered the syringe, absorbent coverings, gloves, and other applicable materials that were used during dosage preparation and administration and placed them into a plastic bag that was subsequently sealed. Due to concern about potential loss of the dosage prior to administration, an RT immediately requested that an MP survey the bag of materials, the capped needle, and the IV lines for residual samarium-153.

The MP measured each of the items in a dose calibrator and determined there was a total of 55 millicuries of residual samarium-153 on the items. Most of the dosage (about 30 millicuries) was measured on the absorbent pad that was under where the syringe connected to the IV. The medical physicist reported the measurement result to the AU, and the AU determined that the patient had only been administered 29 millicuries of samarium-153 lexidronam, which represented an administered dosage that was 66 percent less than the prescribed dosage. The licensee determined that a medical event occurred because the dosage administration resulted in: (1) a dose that differed from the dose that would have resulted from the prescribed dosage by more than 0.5 Sv (50 rem) to an organ or tissue; and (2) the total dosage delivered differed from the prescribed dosage by 20 percent or more.

The licensee had developed, implemented, and maintained a written procedure titled, “Radiopharmacutical Handling and Injection and Administration Procedures” (Procedure) intended to provide high confidence that: (1) the patient's or human research subject's identity is verified before each administration; and (2) each administration is in accordance with the written directive. The Procedure was applicable to samarium-153 lexidronam and other therapeutic nuclear medicine administrations. The RSO stated that the Procedure was implemented for about 250 non-iodine-131 radiopharmaceutical therapy administrations per year over the past few years and no medical events had occurred. However, the inspector identified that the Procedure was silent regarding: (1) response to potential leakage identified prior to dosage administration; (2) the

technique used to prevent syringe disengagement from the syringe shield; and (3) response to syringe disengagement from the syringe shield. In addition, the inspector determined that the Procedure's silence in those areas was a contributing factor to the medical event because if it addressed those areas and it was implemented, the medical event may not have occurred. Since the licensee's Procedure was a contributing factor to the medical event, the inspector determined that it did not provide high confidence that each administration is in accordance with the written directive. In addition, the inspector determined that no programmatic failures occured to implement written directives or procedures for administrations requiring a written directive.

Title 10 of the Code of Federal Regulations (CFR) 35.41(a) states that, for any administration requiring a written directive, licensees are required to develop, implement, and maintain written procedures to provide high confidence that: (1) the patient's or human research subject's identity is verified before each administration; and (2) each administration is in accordance with the written directive. Procedures must meet the requirements described in 10 CFR 35.41(b). The licensee's failure to develop written procedures to provide high confidence that each administration is in accordance with the written directive is a violation of 10 CFR 35.41(a).

b. Medical Event Assessment

The licensee conservatively assigned the AU, RTs, and the physicists whole body and extremity dosimeter badges. The inspector reviewed the dosimeter badge result records from 2008 through July 14, 2011, for those individuals. The whole body and ring badge results were well below 10 percent of the regulatory radiation dose limits for routine activities that were conducted during that period. Therefore, the licensee was not required to monitor the individuals' doses pursuant to 10 CFR 20.1502. The RTs properly wore their whole body and extremity dosimeter badges during their involvement with the medical event; however, the AU forgot to wear her whole body and extremity dosimeter badges during her involvement with the medical event.

The licensee conducted prompt, adequate radiation surveys of the facility and the individuals involved with the dosage spill and the medical event using appropriate, calibrated survey instruments. As a result, the licensee measured 2,000 counts per minute at 1 centimeter from the skin of the AU's right palm. After the AU washed her hands about six times, the licensee measured 500 counts per minute at 1 centimeter from the skin of the AU's right palm. The licensee determined that the 2,000 counts per minute at 1 centimeter from the skin of the AU's right palm existed for ten minutes and, based on a Varskin calculation, the area received 9.5E-4 rads. When the AU's hand was surveyed the next morning, the radiation level was indistinguishable from background in a low background area. The licensee presumed that the 500 counts per minute at 1 centimeter from the skin of the AU's right palm was not removed for 12 hours, and it used Varskin to determine that the resulting dose was 1.89E-2 rads.

In addition, the licensee used Varskin, information obtained during its timed reenactments of the medical event, and it's measurement of about 30 millicuries on the absorbent pad near the AU's hand to determine that the AU received 9.75 rads while her

hand was positioned near the contaminated spot for five minutes. The inspector verified that the licensee's inputs for the dose calculation were adequate.

The licensee also identified contamination on an RT's gloved hand. Based on the licensee's timed reenactment of the RT's involvement with the dosage, the licensee determined that about five millicuries remained on the RT's gloved hand for 20 seconds before the RT removed the contaminated glove and placed it into the aforementioned plastic bag. The licensee used Varskin to calculate that the resulting maximum skin dose was 10.1 rem to a finger tip. The inspector verified that the licensee's inputs for the dose calculation were adequate. The inspector reviewed the RT's extremity dosimeter badge result record for the badge that was worn when the RT handled the dosage, and it indicated a 50 millirem skin dose.

The licensee also identified 40 millirem per hour at the surface of the floor where the AU stood. The floor was scrubbed and the room was secured from access until 10:00 am on November 3, 2011, when the licensee measured 0.5 mR/hr at the surface of a lead brick that shielded the contaminated spot. Based on that reading, the licensee re-opened the room, as a restricted area. On November 16, 2011, the inspector observed an RT use an appropriate, calibrated survey instrument to measure radiation levels that were indistinguishable from background in a low background area at the surface of the lead brick.

The inspector identified several contributing factors to the medical event. As previously discussed in Section 2.2.a., the inspector determined that the failure to include response to potential leakage identified prior to dosage administration, the technique used to prevent syringe disengagement from the syringe shield, and response to syringe disengagement from the syringe shield in the Procedure was a contributing factor to the medical event. In addition, the inspector identified that the other contributing factors were: (1) the dosage's high specific activity; (2) the licensee's removal of the needle from the syringe without first pulling the material out of the needle and into the syringe; (3) the AU's lack of experience with the syringe shield that was used; (4) the inability of the syringe shield to secure the syringe within it; (5) the AU's lack of training on how to prevent the syringe from disengaging from the syringe shield; and (6) the decision to continue preparation for, and administration of, the dosage after identification of potential dosage leakage without first assessing the dosage radioactivity that was spilled.

The licensee determined that the root cause of the medical event was accidental disengagement of the syringe from its shield which caused the syringe to start slipping out of the shield. In addition, the licensee determined that a contributing factor to the medical event was that the AU probably inadvertently put pressure on the syringe plunger while trying to hook up the syringe to the IV connector, resulting in loss of dosage.

2.3 Conclusions

The inspector identified a violation of 10 CFR 35.41(a), concerning the licensee's failure to develop written procedures to provide high confidence that each administration is in

accordance with the written directive. The licensee's response to, and assessment of, the medical event was adequate. No occupational radiation doses exceeded regulatory dose limits as a result of the medical event.

3 Review of Recent Samarium-153 Lexidronam Administrations

3.1 Inspection Scope

The inspector reviewed selected records of about a dozen of the most recent samarium-153 lexidronam administrations that were conducted prior to the medical event. In addition, the inspector interviewed an MP and the RSO to determine if there may have been other similar medical events that had not been identified.

3.2 Observations and Findings

The selected records and the interviews indicated that the licensee implemented its procedure without error. None of the administrations involved dosage spillage based on the licensee's adequate, post dosage administration radiation measurements of the materials used during the dosage administrations, such as absorbent paper that was positioned to absorb spilled dosages. The administered dosages did not result in medical events.

3.3 Conclusions

The inspector determined that the most recent samarium-153 lexidronam administrations that were conducted prior to the medical event did not result in a medical event.

4 Notifications and Reports

4.1 Inspection Scope

The inspector reviewed selected records and interviewed selected staff to understand the licensee's response to its discovery of the medical event. The inspector also reviewed the licensee's notification of the medical event to the NRC Operations Center dated November 3, 2011. In addition, the inspector reviewed the licensee's associated written report of the medical event dated November 17, 2011, to assess compliance with reporting requirements.

4.2 Observations and Findings

On November 2, 2011, the AU notified the patient about the medical event. On November 3, 2011, the licensee notified the NRC Operations Center about the medical event. In addition, on November 3, 2011, the AU notified the referring physician, who was a licensee staff member, about the medical event.

The licensee provided its written report of the medical event in a letter dated November 17, 2011. The inspector determined that the written report was submitted

within 15 days of discovery of the event and it included the information required by 10 CFR 35.3045(d).

4.3 Conclusions

The inspector determined that the licensee provided the notifications and written report as required by 10 CFR 35.3045.

5 Licensee Corrective Actions

5.1 Inspection Scope

The inspector reviewed the licensee's proposed corrective actions to prevent similar events and a similar violation by interviewing selected staff and reviewing the licensee's written report of the medical event dated November 17, 2011.

5.2 Observations and Findings

As immediate corrective action to prevent a similar medical event, the licensee established that only therapists with more experience connecting shielded syringes to the IV connector will do this task rather than a physician until long-term corrective actions are developed and implemented.

In response to the medical event, the AU signed and dated another written directive dated November 2, 2011, for IV administration of samarium-153 lexidronam to the patient who was the subject of the medical event in an effort to make-up for the underdosage. The written directive contained the required information, including a prescribed dosage of 60 millicuries of samarium-153 lexidronam.

On November 9, 2011, the licensee received a unit dosage from its authorized radiopharmacy vendor containing 63.1 millicuries of samarium-153 lexidronam in 1.25 milliliters. The licensee implemented actions to ensure that the administered dosage was in accordance with the written directive including, but not limited to, implementing its aforementioned immediate corrective action for the dosage administration, which was the next administration of samarium-153 lexidronam after the medical event, and measuring 0.09 millirem per hour at 1 meter from the radioactive waste generated from the dosage administration. The dosage was administered without incident on November 9, 2011.

As of the onsite inspection, the licensee's Radiation Oncology physicians, medical physicists, and therapists were still evaluating potential long-term corrective actions to prevent a similar medical event. Radiation Oncology staff were still examining alternative syringe shield designs and ways to better secure the syringe in the syringe shield. For example, the licensee was evaluating use of a Biodex Model Protec IV syringe shield. The licensee was also re-evaluating when to stop and assess the situation before administering dosages when there is indication of a potential problem that could result in a medical event. The licensee anticipated that it would finalize its long-term corrective actions by December 15, 2011.

As of the onsite inspection, the licensee was still determining what long term corrective actions it would take to prevent a similar violation of 10 CFR 35.41(a). For example, the licensee was contemplating what revisions it would make to the Procedure to achieve compliance with the requirement.

5.3 Conclusions

The inspector determined that the licensee implemented immediate corrective actions to prevent a similar violation and a similar medical event. However, the licensee was still determining what long term corrective actions it would take to prevent a similar violation and a similar medical event.

6 Licensee Assessment of Patient Effects

6.1 Inspection Scope

The inspector interviewed the AU and the referring physician and reviewed the licensee's aforementioned written report of the medical event to obtain information about potential adverse effects to the patient as a result of the medical event.

6.2 Observations and Findings

The AU determined that there were no adverse effects to the patient as a result of the medical event and the follow-up dosage administration. In addition, the patient's referring physician stated that she saw the patient after the medical event occurred and the patient told the referring physician that the bone pain was reduced.

6.3 Conclusions

The AU determined that there were no adverse effects to the patient as a result of the medical event.

7 Exit Meeting

At the completion of the on-site inspection, the inspector discussed the preliminary inspection findings in this report with licensee management during an exit meeting. The licensee did not identify any information reviewed during the inspection and proposed for inclusion in this report as proprietary in nature. A final telephonic exit meeting was conducted on November 28, 2011.

Attachment: Partial List of Persons Contacted

Partial List of Persons Contacted

+Bruce Backus, Assistant Vice Chancellor
Caroline Bradfield, Radiation Therapist
+Briana Davis, Health Physicist
+Jose Garcia-Ramirez, Medical Physicist
+Jerry Glotzer, Director, Barnes Jewish Hospital
+Christopher Goddard, Associate General Counsel
+^Susan Langhorst, Ph.D., Radiation Safety Officer
+David Leuchtefeld, Health Physicist
+Trisha Lollo, Vice President, Siteman Cancer Center
+Angel Medina, Radiation Oncology
+Jeff Michalski, Vice Chair, Radiation Oncology
Michelle Murphy, Radiation Therapist
+Sasa Mutic, Radiation Oncology
Ellen Oza, Radiation Therapist
+Susan Richardson, Medical Physicist
+Marie Taylor, M.D.

+ Attended the on-site exit meeting November 18, 2011
^ Participated in the telephone exit meeting on November 28, 2011

Attachment